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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/583,642

06/20/2006

Timothy John Norman

07-1007-WO-US

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20306

7590

10/16/2008

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EXAMINER

DICKINSON, PAUL W

ART UNIT

PAPER NUMBER

1618

MAIL DATE

DELIVERY MODE

10/16/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/583,642	Applicant(s) NORMAN, TIMOTHY JOHN	
	Examiner PAUL DICKINSON	Art Unit 1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 July 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4 and 6-10 is/are pending in the application.
- 4a) Of the above claim(s) 2-4, 6-7, and 9-10 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 and 8 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicant's arguments, filed 7/9/2008, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objects are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

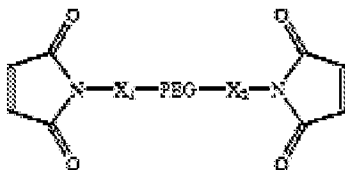
Response to Arguments

Claim Rejections - 35 USC § 112

The rejection of Claims 1 and 8 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement, is maintained.

Applicant argues that the specification defines residue as "that portion of a polymer or of a biologically active moiety which remains after it has undergone a substitution reaction as such terminology is familiar to the person skill in the art".

Applicant's arguments have been fully considered but are not found persuasive. The definition of residue recited in the specification is not limiting. Furthermore, this definition still does not indicate how the base molecular may be changed while remaining a residue. For illustrative purposes only, the Examiner cites US 20030211078 which discloses the compound:



Wherein PEG is polyethylene glycol and X_1 and X_2 are linkers (see Scheme 2). If this polyethylene glycol molecule underwent a substitution reaction, a product could be the terminal maleimide unit. Thus, according to the specification's definition of the term residue, the terminal maleimide unit could be considered a residue of this polyethylene glycol molecule.

Applicant has further amended Claim 1 to include the phrase "residue of polyclonal, monoclonal, multi-valent, multi-specific, humanized or chimeric antibody, a single chain antibody, a Fab' fragment, a Fab' or $F(ab')_2$ fragment, or an epitope-binding fragment" and also the term "maleimide residue". These terms also lack written description as they recite the residue of a parent compound, or the residue of a fragment of a parent compound, for the same reasons as set forth in the previous office action regarding the term "polymer residue". The residues encompassed by these genera are highly variant and the Applicant has not provided a description of the structural relationship of the residues to the parent compounds.

Claim Rejections - 35 USC § 102

The rejection of Claim 1 under 35 U.S.C. 102(b) as being unpatentable over Norman et al (J. Chem. Soc., Chem. Commun., 1995) is maintained.

Applicant argues that neither 1-pentyl-1H-pyrrole-2,5-dione nor $OC(CH_3)_3$ could be considered a polymer residue nor a biologically active moiety as recited in original Claim 1, nor a residue of a polyethylene glycol (PEG) molecule, nor a residue of a

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polyclonal, monoclonal, multi-valent, multi-specific, humanized or chimeric antibody, a single chain antibody, a Fab fragment, a Fab' or F(ab')₂ fragment, or an epitope-binding fragment as recited in amended Claim 1. L¹ has been amended to recite a maleimide residue, and therefore cannot read on the methylene group disclosed by Norman et al. Furthermore, B² is -CONH- in the instant claim, the carbon atom will be bonded to V² and the nitrogen atom bonded to Y². This is reversed in the compound disclosed by Norman et al.

Applicant's arguments have been fully considered but are not found persuasive. As stated above, the terms "residue of a polyethylene glycol (PEG) molecule", "residue of polyclonal, monoclonal, multi-valent, multi-specific, humanized or chimeric antibody, a single chain antibody, a Fab fragment, a Fab' or F(ab')₂ fragment, or an epitope-binding fragment", and a "maleimide residue" are broad terms that encompass a myriad of possibilities. Thus, 1-pentyl-1H-pyrrole-2,5-dione and OC(CH₃)₃ could reasonably be considered residues of polyethylene glycol (PEG) molecules (see **Claim Rejections - 35 USC - 112**). Regarding Z¹, Norman et al discloses reaction of the maleimide with antigen binding fragments of monoclonal antibodies through the maleimide group (see entire document). Regarding the recitation of B² in Instant Claim 1, with only the recitation of the functional group and without further structural information, the broadest reasonable interpretation of -CONH- would be one in which the functional group was oriented in either the fashion wherein the carbon atom is bonded to Y² and the nitrogen atom is bonded to V², or the reverse. Thus, the compound of Norman et al still reads on the compound disclosed in amended Claim 1 as follows:

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 P^1 =1-pentyl-1*H*-pyrrole-2,5-dione A^1 =CONH W^1 =(CH₂)₂ X^1 =N V^1 =covalent bond B^1 =CO Y^1 =(CH₂)₅ L^1 =maleimide Z^1 =Fab' fragment M^1 =(CH₂)₁ P^2 =OC(CH₃)₃ A^2 =CONH W^2 =(CH₂)₄ X^2 =CH V^2 =covalent bond B^2 =NHCO Y^2 =(CH₂)₅ L^2 =maleimide Z^2 =Fab' fragment

n=0

New Grounds of Rejection***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 1 recites "the residue of polyclonal, monoclonal, multi-valent, multi-specific, humanized or chimeric antibody, a single chain antibody, a Fab'

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fragment, a Fab' or F(ab')₂ fragment, or an epitope-binding fragment" and also the term "maleimide residue". It is unclear what a residue of a Fab' fragment, a Fab' or F(ab')₂ fragment, or an epitope-binding fragment, is. A residue of a fragment of a parent compound is indefinite because it is unclear how far one can deviate from the parent compound without the residue of the fragment of the parent compound being so far removed therefrom as to be a completely different compound.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to PAUL DICKINSON whose telephone number is (571)270-3499. The examiner can normally be reached on Mon-Thurs 9:00am-6:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael G. Hartley/
Supervisory Patent Examiner, Art Unit 1618

Paul Dickinson
Examiner
AU 1618

October 13, 2008